UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| JANA GOLDIN, Plaintiff, | : | 12 Civ. 9217 (JPO) |
| -against- | : | MEMORANDUM AND ORDER |
| SMITH & NEPHEW, INC., Defendant. | : | |

J. PAUL OETKEN, District Judge:

This is a products liability case brought by Plaintiff Jana Goldin against Defendant Smith & Nephew, Inc. with respect to the R3 Constrained Acetabular Liner. Defendant has filed a motion to dismiss the Complaint. For the reasons that follow, Defendant's motion is granted and Plaintiff is granted leave to file an amended complaint within the next 60 days.

## I. Background[1]

Following a diagnosis of loss of joint space, Plaintiff underwent right total hip replacement in July 2009. Approximately four months later, Plaintiff developed right groin pain. Testing revealed that she had developed a mental sensitivity. On May 4, 2010, Plaintiff underwent revision and exchange of the metal components with metal and polyethylene components. After this revision surgery, Plaintiff experienced three episodes of recurrent instability, each consistent with anterior dislocation. As a result, her physician recommended that she undergo revision total hip replacement with conversion to a constrained liner.

[1] These facts are taken from the Complaint and assumed to be true for purposes of this opinion. *See Allaire Corp. v. Okumus*, 433 F.3d 248, 249-50 (2d Cir. 2006).

On June 8, 2010, Plaintiff had revision surgery performed at New York University Hospital for Joint Diseases, utilizing the Smith & Nephew 56mm R3 acetabular component with screw fixation, 22mm inside diameter constrained polyethylene liner, and 22mm +4mm modular femoral head. Smith & Nephew had marketed the R3 Constrained Liner for patients at high risk of dislocation due to a history of dislocation, and the R3 Constrainer Liner was recommended to Plaintiff by her surgeon, and accepted by Plaintiff, based on this representation. After the prosthesis was fully implanted, Plaintiff's surgeon placed Plaintiff's hip through a full range of motion and found the components to be secure with excellent stability. An x-ray taken the day of the surgery showed the components to be in good position and alignment, as did x-rays taken at a six-week follow-up visit. At that follow-up visit, Plaintiff was noted to be making good progress toward regaining her range of motion, ambulation, and overall function. She was advised to begin increasing her physical activities and was told that she could return to work on July 26, 2010.

On August 12, 2010, Plaintiff was taking a shower when she experienced excruciating pain in her right hip. She was taken by ambulance to the NYU Hospital for Joint Diseases, where x-rays revealed that the right femoral head had become dislodged from the polyethylene liner. The liner itself was not displaced, leading the surgeon to conclude that the problem was with the constrained liner. Because of this failure of the constrained liner, Plaintiff was advised to undergo another revision surgery. During that surgery, the surgeon checked the acetabular component and found the screws to be secure and in the proper position. A liner with a 20 degree offset was chosen to enhance stability, trial reductions were performed to find components with a good range of motion and stability, and a 40mm modular femoral head and +8mm sleeve were selected and impacted into place. The femoral head was reduced onto the

acetabular component, and the implant checked and found to provide good stability and range of motion. On August 13, 2010, Smith & Nephew issued a voluntary recall of R3 Constrained Acetabular Liners, warning of the risk of intra-operative and post-operative dislocation.

Plaintiff filed suit against Smith & Nephew on November 28, 2012 in the Supreme Court of the State of New York, County of Bronx. Her Complaint alleged causes of action for strict products liability under manufacturing defect, design defect, and failure to warn theories of liability, breach of implied warranty, breach of express warranty, negligence, and violations of New York's consumer protection statute. On December 18, 2010, Smith & Nephew filed a notice of removal to this Court. On January 25, 2013, it filed a motion to dismiss.

## II. Standard of Review

To survive a motion to dismiss pursuant to Federal Rule 12(b)(6), a plaintiff must plead sufficient factual allegations "to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In other words, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. The Court must accept as true all well-pleaded factual allegations in the complaint, and "draw [ ] all inferences in the plaintiff's favor." *Allaire Corp. v. Okumus*, 433 F.3d 248, 249-50 (2d Cir. 2006) (internal quotations omitted). That said, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. In a recent summary of the plausibility standard, the Second Circuit explained that:

> [*Twombly*] stated that a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, but mere labels and conclusions or formulaic recitations of the elements of a cause of action will not do; rather, the complaint's factual allegations must be enough to raise a right to relief above the speculative level, i.e., enough to make the claim plausible.

*Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (quoting *Twombly*, 550 U.S. at 555, 570) (quotation marks and internal citations omitted). The Circuit clarified that this rule "does not impose a probability requirement at the pleading stage; it simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of illegality." *Id.* (citing *Twombly*, 550 U.S. at 556) (quotation marks omitted).

## III. Discussion

### A. Strict Liability

#### 1. Manufacturing Defect

"A manufacturing defect claim is premised on the relevant product being defective because it was not manufactured as designed." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012) (citations omitted); *see also Derienzo v. Trek Bicycle Corp.*, 376 F. Supp. 2d 537, 560 (S.D.N.Y. 2005) ("The crux of a . . . manufacturing defect claim is the product's failure to perform as expected due to an error in the manufacturing process that resulted in a defect."). Under New York law, "[t]o plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (quotation marks and citation omitted). Thus, a manufacturing defect claim is properly dismissed if a plaintiff has

not alleged that "the particular [product] administered to her had a defect as compared to other samples of that [product]." *Reed*, 839 F. Supp. 2d at 577 (quotation marks and citation omitted); *see also Pinello v. Andreas Stihl Ag & Co. KG*, No. 8 Civ. 452, 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011) ("Plaintiff fails to plead which part of the cutoff was defective, or in what way some particular defect caused Plaintiff's injury, as a result of a mishap in the manufacturing process, improper workmanship, or because of defective materials used in construction.").

Plaintiff has failed to allege *any* facts regarding the manufacturing process. The Complaint says nothing about a mishap in the manufacturing process, improper workmanship, or use of defective materials. As a result, there is no reason at all to believe that the particular R3 Constrained Liner used in her surgery was defective as compared to other products manufactured pursuant to the same design. *See Am. Guarantee & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09 Civ. 8357, 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010) ("Plaintiffs have not only failed to specify the defective component but have also failed to adequately allege any deviations from the manufacturing process, improper workmanship, or defective materials."); *Lewis v. Abbott Laboratories*, No. 08 Civ. 7480, 2009 WL 2231701, at *6 (S.D.N.Y. July 24, 2009) ("In the present case, plaintiff does not assert a manufacturing defect claim. She does not allege that the particular Depakote administered to her had a defect as compared to other Depakote."); *Barrett v. Black & Decker (U.S.) Inc.*, No. 06 Civ. 1970, 2008 WL 5170200, at *11 (S.D.N.Y. Dec. 9, 2008) ("Plaintiff fails to plead which part of the saw was defective, or in what way some particular defect caused plaintiff's injury.").

Plaintiff argues that her Complaint nonetheless should survive because she has alleged facts suggesting that the product did not perform as intended and by excluding all other causes

for the product's failure. New York law does recognize the validity of such a circumstantial case for products liability, particularly where, as here, the plaintiff no longer remains in possession of the disputed product. *See Speller ex rel. Miller v. Sears, Roebuck & Co.*, 100 N.Y.2d 38, 41 (2003) ("In order to proceed in the absence of evidence identifying a specific flaw, a plaintiff must prove that the product did not perform as intended and exclude all other causes for the product's failure that are not attributable to defendants."); *see also Riegel v. Medtronic, Inc.*, 451 F.3d 104, 125 (2d Cir. 2006) *aff'd*, 552 U.S. 312 (2008); *Quinlan v. Stryker Corp.*, No. 09 Civ. 7284, 2010 WL 3291807, at *1 (S.D.N.Y. Aug. 12, 2010).

Here, however, Plaintiff has not adequately alleged facts in support of her claim that there is no other possible cause for her product's failure. Rather, she alleges only that several possible causes have been excluded and that her surgeon concluded that "the problem was with the constrained liner." She does not allege that her surgeon viewed the problem with the constrained liner as a manufacturing defect, that the only possible cause of her injury was such a defect in the product, or, most importantly, that the circumstantial case supports the conclusion that this otherwise adequately designed product must have suffered from a manufacturing defect of the sort described above.[2] If Plaintiff is going to rely on the circumstantial theory of liability described in New York case law, she must allege more facts to nudge her claim above the level of speculation and into the realm of the plausible.

**2. Design Defect**

"A design defect claim . . . is premised on a manufacturer's failure to properly design a product, which is then placed on the market despite posing inappropriate risks." *Reed*, 839 F.

[2] Plaintiff deploys this argument in the context of her manufacturing defect claim, but it might be just as applicable to her design defect claim. It would nonetheless fail in that context too, at least at this stage in the litigation and on the basis of this version of the Complaint, for similar reasons.

Supp. 2d at 577 (citations omitted). "Generally, a plaintiff seeking to impose strict liability for a design defect must show that: (1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing the plaintiff's injury." *Pinello*, 2011 WL 1302223, at *15 (citations omitted). It is "well established in New York state courts that in order to establish a *prima facie* case based on a design defect, plaintiff must offer evidence that it was feasible to design the product in a safer manner and that the proposed design would have prevented some of plaintiff's injuries." *Ferracane v. United States*, No. 02 Civ. 1037, 2007 WL 316570, at *5 (E.D.N.Y. Jan. 30, 2007) (quotation marks and citation omitted); *see also Reed*, 839 F. Supp. 2d at 578 ("Plaintiffs' design defect claim also fails for an additional reason. Plaintiffs do not plead facts alleging the existence of a feasible alternative design that would make the product safer, as is required to establish a design defect, under either New York or West Virginia law." (citations omitted)).

Plaintiff has not alleged any facts to demonstrate that the product as designed posed a substantial likelihood of harm or that it was feasible to design the product in a safer manner that would have prevented Plaintiff's injuries. Plaintiff states that the product poses a risk of harm because of its propensity to dislocate, but does not identify any particular problem in the design of the product or identify an alternative design. The bare fact of the voluntary recall does not suffice to prove a design defect. Plaintiff asks the Court to take judicial notice of the fact that "most hip implants do not dislocate during revision surgery," but that is not the proper question. Rather, the question is whether a safer alternative design for *this* product existed—and, more precisely, whether Plaintiff has alleged that fact in her Complaint. In the absence of factual allegations identifying an existing design defect, this claim cannot succeed. *See Am. Guarantee*,

2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010) ("In their Amended Complaint, Plaintiffs do not specify a particular design defect, nor do they make any mention of a feasible alternative design. Plaintiffs do not offer sufficiently detailed facts that would allow a reasonable person to conclude that the product should not have been marketed in its present form."); *Lewis*, 2009 WL 2231701, at *4 ("[P]laintiff's allegations are conclusory. Further, plaintiff has not alleged that it was feasible for Abbott Laboratories to design Depakote in a safer manner. Thus, plaintiff has not met her burden to allege evidence that Depakote is not reasonably safe." (citation omitted)).

**3. Failure to Warn**

To prevail on a failure to warn claim, a plaintiff must prove that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 Fed. App'x 8, 10 (2d Cir. 2011) (citing *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998)). To satisfy these elements, a plaintiff must "prove that the product did not contain adequate warnings." *Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 285 (1st Dep't 2007). Thus, "a failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate." *Reed*, 839 F. Supp. 2d at 575 (citation omitted). "New York recognizes two circumstances in which a manufacturer has no duty to warn of known of foreseeable dangers: first, where the dangers are obvious; and second, where the user is fully aware of those dangers." *Pinello*, 2011 WL 1302223, at *11 (citation omitted).

Plaintiff does not identify the allegedly defective warnings, nor does she allege facts in support of her claim that these warnings were, in fact, defective. She does not identify the promotional materials upon which she and her surgeon allegedly relied, nor does she explain

what warnings those materials contained and how those materials breached a legal obligation. Standing alone, the bare fact that Plaintiff suffered an injury after using a product that had been promoted for patients in her situation does not render the warnings inadequate. *See Reed*, 839 F. Supp. 2d at 576-77 ("To cut to the chase, the fact . . . that Ms. Reed suffered from certain conditions that were also identified risks of ingesting Lybrel is tragic, but cannot *alone* make plausible a claim that defendants misrepresented or hid those risks in some way."); *Am. Guarantee*, 2010 WL 5480775, at *3 ("Plaintiffs have not pleaded sufficient facts to allow the Court to make a reasonable inference that the lack of warning was a substantial factor in causing the accident. As Plaintiffs have not adequately specified the danger that was not warned against, they cannot state a plausible claim for failure to warn.").

**B. Breach of Implied Warranty**

An "implied warranty is breached where the product in question is not fit for the ordinary purpose for which it is to be used." *Plemmons v. Steelcase Inc.*, No. 04 Civ. 4023, 2007 WL 950137, at *3 (S.D.N.Y. Mar. 29, 2007) (citation omitted). To succeed on an implied warranty claim, Plaintiff must establish: "(1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." *Id.* at *3 (citations and internal quotations omitted). One court has observed that "liability under strict products liability and implied warranty theory are essentially the same." *Pinello*, 2011 WL 1302223, at *17 (citation omitted); *see Lewis*, 2009 WL 2231701, at *6 ("[P]laintiff has not pleaded necessary elements to support a design, failure to warn, or manufacturing defect claim. Therefore, plaintiff has failed to plead an essential element of her breach of implied warranty claim."). Plaintiff has not adequately

pleaded facts in support of her allegation that the R3 Constrained Acetabular Liner was defective. Therefore, this claim must be dismissed.

**C. Breach of Express Warranty**

Any "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." N.Y.U.C.C. § 2–313(1)(a). "To establish the breach of an express warranty, the plaintiff must show that there was an 'affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase' and that the warranty was relied upon to the plaintiff's detriment." *Barrett*, 2008 WL 5170200, at *12 (citations omitted) (alteration in original). In other words, "[a] successful claim of a breach of express warranty requires proof that an express warranty existed, was breached, and that plaintiff had relied on that warranty." *Reed*, 839 F. Supp. 2d at 578 (citations omitted). "The plaintiff must set forth the terms of the warranty upon which he relied." *Id.* (citations omitted). Where a "[p]laintiff does not identify the terms of the purported warranty he claims to have relied on," any "conclusory allegation . . . for breach of express warranty [must] be dismissed." *Pinello*, 2011 WL 1302223, at *17. Further, "a successful breach of warranty claim requires that the product be defective." *Reed*, 839 F. Supp. 2d at 578 (citing *Plemmons*, 2007 WL 950137, at *5). Plaintiff has not alleged with sufficient specificity the requisite representation by Smith & Nephew, nor has Plaintiff alleged sufficient facts in support of her allegation that the R3 Constrained Acetabular Liner was, in fact, defective. Accordingly, this claim must be dismissed.

**D. Negligence**

"New York courts generally consider strict products liability and negligence claims to be 'functionally synonymous.'" *Pinello*, 2011 WL 1302223, at *16 (quoting *Penny v. Ford Motor*

*Co.*, 639 N.Y.S.2d 250 (1995)). "[A] negligence claim requires the plaintiff to show that (1) the manufacturer owed plaintiff a duty to exercise reasonable care; (2) the manufacturer breached that duty by failing to use reasonable care so that the product was rendered defective; (3) the defect was the proximate cause of the plaintiff's injury; and (4) plaintiff suffered loss or damage." *Lewis*, 2009 WL 2231701, at *3 (quotation marks and citations omitted). Where a plaintiff fails to plead "facts making it plausible (1) that anything that defendants did or failed to do fell below the standard of reasonable care or (2) that the [disputed product] was defective in any way including in its warnings, manufacture, or design," she cannot state a negligence claim under New York law. *Reed*, 839 F. Supp. 2d at 578 n.6 (citation omitted). Plaintiff alleges that Smith & Nephew knew or should have known about the risks associated with the R3 Constrained Acetabular Liner was defective, but does not offer factual allegations to support this legal conclusion. Further, as explained above, Plaintiff has failed to allege sufficient facts in support of her allegation that the R3 Constrained Acetabular Liner was, in fact, defective. This claim must be dismissed.

**E. Consumer Protection Statute**

Plaintiff's final cause of action invokes New York General Business Law § 349. In this cause of action, Plaintiff alleges that Smith & Nephew "failed to adequately warn consumers and the medical community of the safety risks associated with the R3 Constrained Acetabular Liner" and made "false and misleading representations and omissions of material facts regarding the safety and potential risks of the R3 Constrained Acetabular Liner." For the reasons stated above with respect to Plaintiff's other allegations, this claim must be dismissed.

### F. Leave to Amend

Plaintiff requests leave to address any pleading deficiencies in an amended complaint. Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend a pleading "shall be freely given when justice so requires." There has been no prior dismissal of the Complaint, Plaintiff has not previously amended its pleadings, and Defendant has not demonstrated that it would be prejudicial, futile, or otherwise unfair for Plaintiff to be afforded leave to amend. Indeed, given that the Complaint was drafted as part of a state court filing, but is now subject to the higher pleading standards applicable in federal court, it would be particularly consistent with principles of fairness and justice to afford Plaintiff an opportunity to file an amended complaint. Whether or not the Plaintiff can actually cure the deficiencies in the Complaint remains to be seen, but because the Court bases its dismissal of the Complaint primarily on Plaintiff's failure to allege non-conclusory facts in support of its claims, leave to replead is appropriate. *See Reed*, 839 F. Supp. 2d at 580 (noting "the high value to be placed on merit resolution of cases").

## IV. Conclusion

For the foregoing reasons, Defendants' motion to dismiss is GRANTED without prejudice. Plaintiff is granted to leave to file an amended complaint within the next 60 days.

The Clerk of Court is directed to close the motion at Dkt. No. 9.

SO ORDERED.

Dated: New York, New York
April 24, 2013

J. PAUL OETKEN
United States District Judge